

What Is Claimed Is:

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12	1.	A method of closed-chest surgical intervention within an internal cavity heart or great vessel, the method comprising:
of a pa	atieht's	heart or great vessel, the method comprising:

establishing cardiopulmonary bypass;

arresting the patient's heart;

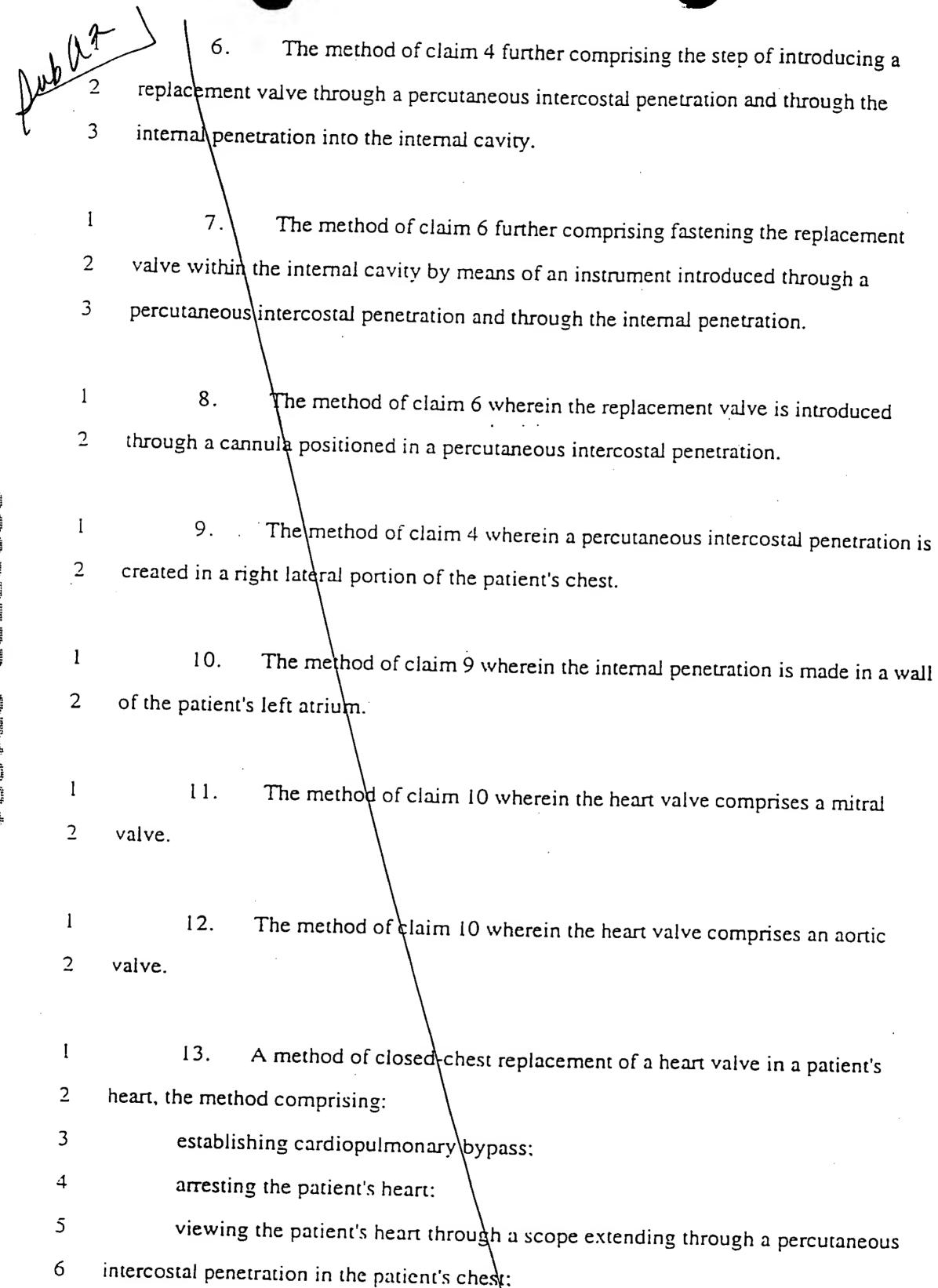
viewing an internal portion of the patient's chest through a scope extending through a percutaneous intercostal penetration in the patient's chest;

forming an internal penetration in a wall of the heart or great vessel using cutting means introduced through a percutaneous intercostal penetration in the patient's chest; and

introducing an interventional tool through a percutaneous intercostal penetration and through the internal penetration to perform a surgical procedure within the internal cavity under visualization by means of said scope.

- The method of claim I wherein the patient's heart is arrested by occluding the patient's aorta between the patient's coronary arteries and the patient's brachiocephalic artery with an expandable member on a distal end of an endovascular catheter, and perfusing the patient's myocardium with cardioplegic fluid.
 - The method of claim wherein the interventional tool is introduced through a cannula positioned in a percutaneous intercostal penetration.
- The method of claim 1 wherein the surgical procedure comprises surgically treating a heart valve.
- The method of claim 4 further comprising the step of removing at least a portion of the heart valve by means of a cutting tool introduced through a percutaneous intercostal penetration and through the internal penetration.





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forming an internal penetration through a wall of the patient's heart using a cutting tool introduced through a percutaneous intercostal penetration in the patient's chest;

positioning a replacement valve through a percutaneous intercostal penetration in the patient's chest and through the internal penetration into a chamber of the heart; and

securing the replacement valve in a valve position in the heart.

- 14. The method of claim 13 wherein the patient's heart is arrested by occluding the patient's norta between the patient's coronary arteries and the patient's brachiocephalic artery with an expandable member on a distal end of an endovascular catheter, and perfusing the patient's myocardium with cardioplegic fluid.
- 15. The method of claim 13 wherein the heart valve comprises a mitral valve, the valve position comprising a mitral valve position.
- 1 16. The method of claim 15 wherein the chamber comprises a left atrium of 2 the patient's heart.
- 17. The method of claim 13 wherein the percutaneous intercostal penetration is disposed in a right lateral portion of the patient's chest.
- 1 18. The method of claim 13 further comprising the step of removing at least a portion of the patient's heart valve using a cutting tool introduced through a percutaneous intercostal penetration and through the internal penetration.
- 19. The method of claim 13 further comprising sizing the patient's heart valve by means of a sizing instrument introduced through a percutaneous intercostal penetration and through the internal penetration.

- 20. The method of claim 13 wherein the replacement valve is positioned by means of an introducer, the introducer comprising an elongated shaft and means at a distal end of the shaft for holding the replacement valve.
 - 1 21. The method of claim 13 wherein the step of fastening comprises 2 suturing the replacement valve to an annulus at the valve position.
 - The method of claim 21 wherein the step of suturing comprises applying a plurality of sutures to an annulus at the valve position, drawing the sutures out of the patient's body through the internal penetration and through a percutaneous intercostal penetration, and applying the sutures to the replacement valve.
 - The method of claim 22 further comprising radially arranging the sutures in spaced-apart locations about an organizing ring disposed outside of the patient's body.
 - The method of claim 23 further comprising holding the sutures in tension in the organizing ring as the replacement valve is positioned in the valve position.
 - 25. The method of claim 13 wherein the replacement valve is introduced through a cannula positioned in a percutaneous intercostal penetration.
 - 26. A system for closed-chest surgical intervention within a patient's heart or great vessel, the system comprising:
 - means for forming a percutaneous penetration in an intercostal space in the patient's chest;
 - a visualization scope configured to pass through an intercostal space in the

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patient's chest for viewing an internal chest cavity;

means for arresting the patient's heart from a location outside of the chest cavity;

a cardiopulmonary bypass system, including means for delivering oxygenated blood to the patient's arterial system;

cutting means positionable through a percutaneous intercostal penetration into the chest davity for forming an internal penetration in a wall of the patient's heart or great vessel, and

interventional means positionable through a percutaneous intercostal penetration and through the internal penetration for performing a surgical procedure within the heart or great vessel.

- 27. The system of claim 26 wherein the means for arresting the heart comprises an endovascular catheter having expandable means for occluding the patient's ascending aorta between the patient's coronary arteries and the patient's brachiocephalic artery, and an internal lumen for delivering cardioplegic fluid into the ascending aorta upstream of the expandable means.
- 28. The system of claim 26 wherein the interventional means comprises means for securing a replacement valve at a valve location within the patient's heart.
- The system of claim 28 further comprising a cannula positionable in a percutaneous intercostal penetration, the cannula having a lumen therein through which the replacement valve may be introduced into the internal chest cavity.
- 1 30. The system of claim 28 wherein the replacement valve comprises an
 2 annular portion for attachment to a valve annulus in the heart, the annular portion
 3 having an outer diameter, wherein the lumen in the cannula has a cross-sectional height
 4 at least equal to the outer diameter, and a cross-sectional width less than the width of

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the intercostal space.

- 31. The system of claim 28 further comprising cutting means positionable through a percutaneous intercostal penetration and through the internal penetration for removing at least a portion of the patient's heart valve.
- 32. The system of claim 28 further comprising means positionable through a percutaneous intercostal penetration and through the internal penetration for sizing a valve annulus of the patient's heart valve.
- 33. The system of claim 32 wherein the sizing means comprises an elongated shaft and sizing means at a distal end of the shaft, wherein the shaft and sizing means may be introduced through a percutaneous intercostal penetration and through the internal penetration to position the sizing means near the valve annulus.
- 34. The system of claim 28 further comprising means for introducing the replacement valve into the patient's heart, the introducing means comprising an elongated shaft having means at a distal end thereof for releasably holding the replacement valve.
- 35. The system of claim 34 wherein the introducing means further comprises means actuated from a proximal end of the shaft for pivoting the replacement valve relative to the shaft from a first position for introduction through a percutaneous intercostal penetration to a second position for attachment at the valve location.
 - 36. The system of claim 28 wherein the means for securing the replacement valve comprises means positionable through a percutaneous intercostal penetration for suturing the replacement valve to a valve annulus at the valve location.



- 37. The system of claim 36 further comprising organizing means for maintaining sutures in spaced-apart positions outside of the chest cavity after the sutures have been applied to the valve annulus.
- The system of claim 37 wherein the organizing means is fixed to a proximal end of a cannula disposed in a percutaneous intercostal penetration, the cannula having a lumen through which the replacement valve may be introduced into the chest cavity.
- 39. The system of claim 37 further comprising means on the organizing means for maintaining tension on ends of the sutures to facilitate advancing the replacement valve along the sutures into the patient's heart.
- 1 40. The system of claim 26 further comprising retraction means positionable 2 through an intercostal space in the patient's chest for opening the internal penetration in 3 the wall of the heart or great vessel.
- 1 41. The system of claim 26 wherein the interventional means is configured 2 to reach the interior of the heart or great vessel from a percutaneous penetration in a 3 right lateral portion of the patient's chest.
- 1 42. The system of claim 41 wherein the interventional means is at least 2 about 20 cm in length.
- 1 43. A percutaneous access cannula to facilitate closed-chest replacement of a heart valve in a patient's heart, the access cannula comprising:
- a cannula body configured for placement in an intercostal space in the patient's

 chest, the cannula body having a distal end, a proximal end, and a lumen extending

 therebetween, the lumen being configured to allow passage of a replacement valve



therethrough; and

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an obturator positionable in the lumen, the obturator having a cross-sectional width less than the width of the intercostal space and a cross-sectional height greater than the cross-sectional width.

- The access cannula of claim 43 wherein the valve prosthesis has an annular attachment portion with an outer diameter, the obturator having a cross-sectional height at least equal to the outer diameter.
- 1 45. The access cannula of claim 43 wherein the cross-sectional height is about 2 to 6 times the cross-sectional width.
- 46. The access cannula of claim 43 wherein the obturator has a generally rectangular cross-section.
- 47. The access cannula of claim 43 wherein the obturator has a generally oval cross-section.
- 1 48. The access cannula of claim 44 wherein the lumen in the cannula body
 2 has a cross-sectional shape in an unstressed condition with a width less than the width
 3 of the intercostal space and a height greater than the outer diameter of the valve
 4 prosthesis.
- 1 49. The access cannula of claim 48 wherein the lumen has a generally rectangular cross-section.
- The access cannula of claim 48 wherein the lumen has a generally ovalshaped cross-section.

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The access cannula of claim 48 wherein the cross-sectional height of the lumen is 2 to 6 times the cross-sectional width of the lumen.

- The access cannula of claim 43 further comprising means at the proximal end of the cannula body for retaining a plurality of sutures extending through the lumen in a spaced apart relationship.
- The access cannula of claim 52 wherein the suture retaining means comprises a plurality of slots in the proximal end of the cannula body in circumferentially spaced positions around the lumen.
- The access cannula of claim 52 further comprising means at the proximal end of the cannula body for maintaining tension on the sutures.
 - 55. The access can rula of claim 54 wherein the means for maintaining tension comprises an organizing ring having an interior passage through which the sutures may extend and a plurality of means circumferentially spaced around the passage for frictionally engaging the sutures.
- The access cannula of claim 55 wherein the organizing ring comprises
 an inner ring, an outer ring rotatably coupled to the inner ring, a first plurality of
 apertures circumferentially spaced about the inner ring, and a second plurality of
 apertures circumferentially spaced about the outer ring, the first and second plurality of
 apertures being aligned when the outer ring is in a first rotational position, and nonaligned when the outer ring is in a second rotational position.
- 57. A cannula system to facilitate surgical intervention in a patient's body cavity, the cannula system comprising:
- a cannula body having a distal end, a proximal end, and a lumen therebetween,

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the lumen being configured for introduction of surgical instruments therethrough; and organizer means at the proximal end of the cannula body for retaining a plurality of sutures extending through the lumen from the body cavity in spaced apart positions outside of the body cavity.

- 58 The cannula system of claim 57 wherein the cannula body is configured for positioning in an intercostal space in the patient's chest.
- 59. The cannula system of claim 57 wherein the organizer means comprises a first organizing ring having an interior passage and a plurality of suture retaining means circumferentially spaced about the interior passage.
- 60. The cannula system of claim 59 wherein the first organizing ring is fixed to the proximal end of the cannula body with the interior passage aligned with the lumen.
- 61. The cannula system of claim 59 wherein the suture retaining means comprise a plurality of slots in the first organizing ring circumferentially spaced about the interior passage.
- 62. The cannula system of claim 60 further comprising means at the 2 proximal end of the cannula body for maintaining the sutures in tension.
- 63. The cannula system of claim 62 wherein the means for maintaining the 2 sutures in tension comprises a second organizing ring spaced apart from the first organizing ring, the second organizing ring having an interior passage and a plurality of means circumferentially spaced about the interior passage for holding the sutures in tension.

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,	64. The cannula system of claim 63 wherein the means for holding the
suture	in tension comprise slits in the second organizing ring for frictionally engaging
the su	tures.

- The cannula system of claim 62 wherein the means for maintaining the 65. sutures in tension comprises slits in the first organizing ring for frictionally engaging 2 3 the sutures.
- The dannula system of claim 58 further comprising means for holding a 66. replacement valve outside the chest in proximity to the organizer means, whereby a 2 suture extending from the body cavity through the lumen in the cannula may be applied 3 to the replacement valve and secured in the organizer means.
- The cannula system of claim 66 wherein the lumen is configured to 67. facilitate introduction of the replacement valve therethrough into the body cavity. 2
 - A thoracoscopic device for placement of a replacement valve in a valve 68. position of a patient's heart, the thoracoscopic device comprising:
 - an elongated handle having a distal end and a proximal end, the handle configured for positioning through an intercostal space in the patient's chest; and means at the distal end of the handle for releasably holding a replacement valve in an orientation for introduction through the intercostal space.
- The thoracoscopic device of claim 68 wherein the handle is at least about 69. 20 cm in length. 2
 - The thoracoscopic device of claim 68 further comprising means for 70. pivoting the replacement valve relative to the handle from a first orientation for introduction through the intercostal space, to a second orientation for placement in the

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valve position

4	Valve position.
1	71. The thoracoscopic device of claim 68 wherein the pivoting means
2	includes an actuator disposed at the proximal end of the handle.
1	72. The thoracoscopic device of claim 68 further comprising means at the
2	proximal end of the handle for releasing the replacement valve from the holding means.
1	73. A prosthesis assembly for closed-chest replacement of a heart valve, the
2	prosthesis assembly comprising:
3	a replacement valve having an annular attachment portion and a movable valve
4	portion coupled to the attackment portion; and
5	holder means releasably mounted to the attachment portion, wherein the holder
6	means is configured to allow introduction of the replacement valve through an
7	intercostal space in the patient's chest.
1	74. The prosthesis assembly of claim 73 wherein the intercostal space has
2	an intercostal width, the replacement valve and holder means together having a profile
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The prosthesis assembly of claim 74 wherein the attachment portion of the replacement valve has an outer diameter which is greater than the intercostal width.

with a width less than the intercostal width.

- The prosthesis assembly of claim 73 wherein the holder means
 comprises an elongated handle having a distal end mounted to the replacement valve
 and a proximal end opposite the distal end, the handle being configured for introducing
 the replacement valve into the patient's heart through the intercostal space.
 - 77. The prosthesis assembly of claim 76 wherein the handle is at least about

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2 20 cm in length so as to allow positioning the replacement valve in the heart from a 3 right lateral portion of the chest.

- 78. The prosthesis assembly of claim 76 wherein the handle comprises means for releasing the replacement valve, the releasing means being configured for actuation from a proximal end of the handle.
- The prosthesis assembly of claim 76 wherein the handle comprises
 means for pivoting the replacement valve from a first orientation for introduction
 through the intercostal space to a second orientation for attachment within the patient's
 heart, the pivoting means being configured for actuation from a proximal end of the
 handle.
- 1 80. The prosthesis assembly of claim 73 wherein the intercostal space is less 2 than about 20 mm in width.
- 1 81. The prosthesis assembly of claim 73 wherein the replacement valve and 2 holding means are contained in a sterile pack.